

Appl. No. 10/730,567
Amdt. Dated: 03/16/2006
Reply to Office Action of December 19, 2005

REMARKS

In the specification, paragraph numbers [0002] to [0008], [0010], [0012], [0016], [0018], [0028], [0031], [0033], [0034], [0037], [0039], [0044] to [0048], [0055] to [0057], [0065] and [0068] have been amended to correct minor editorial problems.

Claim Objections

The Office has objected to claims 68 and 69 due to informalities in the wording. Applicant respectfully submits that claims 68 and 69 have been cancelled. Thus, the objection to these claims is now moot.

Claims Rejections - 35 USC §112 First Paragraph

The first paragraph of 35 U.S.C. 112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. [emphasis added].

This section of the statute requires that the specification include the following:

- (A) A written description of the invention;
- (B) The manner and process of making and using the invention (the enablement requirement); and
- (C) The best mode contemplated by the inventor of carrying out his invention.

MPEP§2161

The Office has rejected claims 58, 68, 69 and 79-80 under 35 USC 112, first paragraph, as not providing enablement for a method of treating any dysautonomic disorder. The Office has also deemed that these claims are not enabled for treating hypertension in any mammal in any concentration.

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Applicant respectfully submits that claims 58, 68, 69 and 79-80 have been cancelled. Thus, the rejection to these claims under 35 USC 112, first paragraph, is now moot. Applicant has added new claims 81, 82 and 83, which indicate a method of treating hypertension in a human by administering a composition consisting of secretin in an amount of at least 1U/kg of body weight of the human. Applicant respectfully submits that new claims 81, 82 and 83 are enabling under 35 USC 112, first paragraph.

Claims Rejections - 35 USC §102(b)

The Office rejected claims 69 and 79-80 under 35 U.S.C. 102(e) as being anticipated by Beck et al. (US 6,197,746). A rejection based on anticipation requires that a single reference teach every element of the claim (MPEP § 2131). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Or stated in another way, a "claim is anticipated only if each and every element as set forth in the claim is found, . . . described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant respectfully submits that claims 69 and 79-80 have been cancelled. Thus, the rejection to these claims under 35 USC 102(e) is now moot. Applicant respectfully submits that new claims 81, 82 and 83 are not anticipated by the '746 patent of Beck et al. as Beck does not teach or disclose the use of secretin to treat hypertension in a human.

Claim Rejections – 35 USC § 103(a)

The Office has quoted the statute from 35 USC 103(a), which is referenced herein. The Office has rejected claims 61, 68-69, 72 and 79-80 as being unpatentable over Barlow (1926). Applicant respectfully submits that claims 61, 68-69, 72 and 79-80 have been cancelled. Thus, the rejection to these claims under 35 USC 103(a) is now moot.

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Applicant has carefully considered the Office rejections and respectfully submits that new claims 81, 82 and 83, as supported by the arguments herein, are distinguishable from the cited reference.

According to the MPEP §2143.01, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art."

A useful presentation for the proper standard for determining obviousness under 35 USC §103(a) can be illustrated as follows:

1. Determining the scope and contents of the prior art;
2. Ascertaining the differences between the prior art and the claims at issue;
3. Resolving the level of ordinary skill in the pertinent art; and
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

Applicant respectfully submits that new claims 81, 82 and 83 are patentable over Barlow (1926) as Barlow does not teach or disclose the administration of secretin to hypertensive subjects. Furthermore, Barlow teaches the use of secretin containing a small amount of vasodilatin. As noted by the Examiner, the Ferring secretin used in the present application is not known to contain any amount of vasodilatin. Thus, Applicant respectfully submits that one with ordinary skill in the art would not have been motivated to rely on Barlow, nor would they have had a reasonable expectation that Ferring secretin, which is not known to contain vasodilatin, would have lowered blood pressure in a hypertensive patient.

Substance of Interview (MPEP 713.04)

As noted in 37 CFR 1.133, the Applicant is required to make the Substance of the Interview of record in the application file. To ensure compliance therewith, Applicant wishes to note the following:

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- 1) A telephonic interview was conducted on February 15, 2006 between Attorney Grasso and Examiner Patricia Leith.
- 2) New claims 81, 82 and 83 were discussed and it was agreed to amend new claim 83 to add "secretin" to the wording.
- 3) It was agreed that such amendment would likely place claim 83 in condition for allowance.
- 4) The Examiner indicated that new claims 81 and 82 would require evaluation in light of the cited prior art.

Telephone Interview

Present Office policy places great emphasis on telephone interviews initiated by the examiner. For this reason, it is not necessary for an attorney to request a telephone interview. Examiners are not required to note or acknowledge requests for telephone calls or state reasons why such proposed telephone interviews would not be considered effective to advance prosecution. However, it is desirable for an attorney to call the examiner if the attorney feels the call will be beneficial to advance prosecution of the application. MPEP§408

Applicant believes the above amendments and remarks to be fully responsive to the Office Action, thereby placing this application in condition for allowance. No new matter is added. Applicant requests speedy reconsideration, and further requests that Examiner contact its attorney by telephone, facsimile, or email for quickest resolution, if there are any remaining issues.

Respectfully submitted,



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